

AMENDED IN SENATE MARCH 17, 1998

SENATE BILL

No. 1606

Introduced by Senator Lewis

February 11, 1998

An act to ~~amend Sections 4019, 4077, and 4119~~ *add Article 12.5 (commencing with Section 4177) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacy.*

LEGISLATIVE COUNSEL'S DIGEST

SB 1606, as amended, Lewis. Pharmacy: automated drug delivery systems.

Existing law, the Pharmacy Law, provides for the licensing and regulation of the practice of pharmacy, under the jurisdiction of the California State Board of Pharmacy. *It prescribes requirements for the dispensing of drugs, as specified.*

~~Existing law provides that an order entered on the chart or medical record of a patient registered in a hospital or a patient under emergency treatment in the hospital, by or on the order of a practitioner authorized by law to prescribe drugs is an authorization for the administration of the drug from hospital floor or ward stocks furnished by the hospital pharmacy or under licensure granted, as specified.~~

~~This bill would make that provision additionally applicable authorize, with respect to a patient in a an agreement between a pharmacy and health facility, defined to include convalescence and rehabilitation facilities. It would also authorize, the administration of the drug drugs from an automated drug-delivery dispensing system in the facility, and~~

~~the furnishing of the drug by a consulting pharmacy, and would make related changes subject to specified conditions.~~

~~Existing law prohibits a pharmacist from dispensing any prescription except in a container that meets the requirements of state and federal law and is correctly labeled. Certain devices are exempted from that requirement.~~

~~This bill would additionally exempt over-the-counter drugs and drugs that bear a caution legend and are withdrawn from an automated drug delivery system that possesses certain patient safeguards.~~

~~Existing law authorizes a pharmacy to furnish a dangerous drug or dangerous device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container, and limits the number or oral dosage form and suppository form drugs in the emergency supply to 24.~~

~~This bill would provide that the limitation does not apply to an automated drug delivery system if the system provides for security and accountability and provides for a review of the medications for potential adverse drug reactions prior to their withdrawal from the system.~~

~~Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.~~

The people of the State of California do enact as follows:

1 ~~SECTION 1. Section 4019 of the Business and~~
2 ~~SECTION 1. Article 12.5 (commencing with Section~~
3 ~~4177) is added to Chapter 9 of Division 2 of the Business~~
4 ~~and Professions Code, to read:~~

5
6 *Article 12.5. Automated Drug Dispensing*

7
8 ~~4177. As used in this article, “automated drug~~
9 ~~dispensing system” means a mechanical system that~~
10 ~~performs operations or activities, other than~~
11 ~~compounding or administration, relative to the storage,~~
12 ~~dispensing, or distribution of medications that collect,~~
13 ~~control, and maintain all transaction information as well~~
14 ~~as provide for security and accountability of drug~~
15 ~~products.~~

1 4177.5. A pharmacy and a health facility licensed
2 pursuant to subdivisions (c) and (d) of Section 1250 of the
3 Health and Safety Code that have entered into an
4 agreement for the provision of drugs to the patients of the
5 facility may use an automated drug dispensing system
6 located in the facility if all of the following conditions are
7 met:

8 (a) The drugs in the automated drug dispensing
9 system are owned by the pharmacy until they are
10 dispensed for patient use.

11 (b) The automated drug dispensing system has
12 adequate security systems and procedures, evidenced by
13 written policies and procedures, to do the following:

14 (1) Prevent unauthorized access.

15 (2) Comply with federal and state regulations.

16 (3) Maintain patient confidentiality.

17 (4) Assure compliance with the requirements of this
18 section.

19 (c) Accountability for the drugs dispensed from the
20 automated drug dispensing systems shall be the
21 responsibility of the pharmacist-in-charge of the
22 pharmacy.

23 (d) Filling and stocking of all medications in the
24 automated drug dispensing system shall be performed by
25 a pharmacist or pharmacy technician acting under the
26 direct supervision of a pharmacist. For purposes of this
27 section, "direct supervision" means the pharmacist shall
28 verify that the filling and stocking of the drugs is
29 replacement stock for drugs documented as dispensed
30 from the system.

31 (e) Drugs dispensed from the automated dispensing
32 system shall be limited to the following:

33 (1) Drugs ordered by a prescriber for a patient of the
34 facility for administration at a time prior to the next
35 readily scheduled delivery from the pharmacy.

36 (2) Drugs that a prescriber has ordered for a patient
37 on an as needed basis, provided the utilization of those
38 drugs is subject to ongoing review by a pharmacist.

1 (3) Drugs dispensed pursuant to the order of a
2 prescriber for emergency administration to a patient of
3 the facility.

4 (f) Except for drugs dispensed pursuant to paragraph
5 (3) of subdivision (e), access to the drugs in the
6 automated drug dispensing system shall require
7 authorization from a pharmacist who is an employee or
8 agent of the pharmacy and who has reviewed the
9 prescriber's order.

10 (g) Review of the operation and maintenance of the
11 automated drug dispensing system shall be the
12 responsibility of the consultant pharmacist retained by
13 the licensed health facility. That review shall include a
14 physical inventory of the drugs in the automated drug
15 dispensing system and a review of the dispensing and
16 filling and stocking records no less than once every
17 calendar quarter in order to verify the security
18 accountability of the system.

19 4178. Jurisdiction over the ownership, security,
20 accountability, and any other aspect of the operation of
21 automated drug dispensing systems shall be with the
22 board. Other agencies with regulatory authority over
23 facilities licensed pursuant to subdivision (c) or (d) of
24 Section 1250 of the Health and Safety Code shall have
25 access to records consistent with their authority, and shall
26 report any problems with the operation of the system to
27 the board.

28 4178.5 An automated drug dispensing system that
29 meets the requirements of Section 4177.5 shall not be
30 construed to be an emergency supplies container as
31 defined in Section 1261.5 of the Health and Safety Code
32 and shall not be subject to any limitations imposed by that
33 section.

34 4179. Drugs dispensed from an automated drug
35 dispensing system that meets the requirements of Section
36 4177.5 shall not be subject to the labeling requirements of
37 Section 4076 or Section 111480 of the Health and Safety
38 Code if the automated drug dispensing system contains
39 the information required by those sections or if the



1 *information is otherwise readily available at the time of*
2 *drug administration.*

3 ~~Professions Code is amended to read:~~

4 ~~4019. An “order,” entered on the chart or medical~~
5 ~~record of a patient registered in a hospital, a patient in a~~
6 ~~health facility as defined in Section 1250 of the Health and~~
7 ~~Safety Code, or a patient under emergency treatment in~~
8 ~~the hospital, by or on the order of a practitioner~~
9 ~~authorized by law to prescribe drugs, shall be~~
10 ~~authorization for the administration of the drug from~~
11 ~~hospital floor, automated drug delivery system, or ward~~
12 ~~stocks furnished by the hospital or consulting pharmacy~~
13 ~~or under licensure granted under Section 4056, and shall~~
14 ~~be considered to be a prescription if the medication is to~~
15 ~~be furnished directly to the patient by the hospital~~
16 ~~pharmacy, consulting pharmacy, or another pharmacy~~
17 ~~furnishing prescribed drugs for hospital or health facility~~
18 ~~patients; provided that the chart or medical record of the~~
19 ~~patient contains all of the information required by~~
20 ~~Sections 4040 and 4070 and the order is signed by the~~
21 ~~practitioner authorized by law to prescribe drugs, if he or~~
22 ~~she is present when the drugs are given, or if he or she is~~
23 ~~not present, then on his or her next visit to the hospital or~~
24 ~~health facility.~~

25 ~~SEC. 2. Section 4077 of the Business and Professions~~
26 ~~Code is amended to read:~~

27 ~~4077. (a) Except as provided in subdivisions (b) and~~
28 ~~(c), no person shall dispense any dangerous drug upon~~
29 ~~prescription except in a container correctly labeled with~~
30 ~~the information required by Section 4076.~~

31 ~~(b) Physicians, dentists, podiatrists, and veterinarians~~
32 ~~may personally furnish any dangerous drug prescribed by~~
33 ~~them to the patient for whom prescribed, provided that~~
34 ~~the drug is properly labeled to show all information~~
35 ~~required in Section 4076 except the prescription number.~~

36 ~~(c) Devices that bear the legend “Caution: federal law~~
37 ~~restricts this device to sale by or on the order of a~~
38 ~~____,” or words of similar meaning, or~~
39 ~~over-the-counter drugs or drugs that bear the legend~~
40 ~~“Caution: Federal law prohibits dispensing without a~~

1 prescription” or words of similar meaning if those drugs
2 are administered directly to the patient and withdrawn
3 from an automated drug delivery system that provides for
4 security and accountability of drug products and there is
5 a function which provides for a review of those
6 medications for potential adverse drug reactions prior to
7 their withdrawal from the system, and are exempt from
8 the requirements of Section 4076, and Section 111480 of
9 the Health and Safety Code, when provided to patients
10 in skilled nursing facilities or intermediate care facilities
11 licensed pursuant to Chapter 2 (commencing with
12 Section 1250) of Division 2 of the Health and Safety Code.

13 (d) The following notification shall be affixed to all
14 quantities of dimethyl sulfoxide (DMSO) prescribed by
15 a physician, or dispensed by a pharmacy pursuant to the
16 order of a physician in California: “Warning: DMSO may
17 be hazardous to your health. Follow the directions of the
18 physician who prescribed the DMSO for you.”

19 (e) The label of any retail package of DMSO shall
20 include appropriate precautionary measures for proper
21 handling and first aid treatment and a warning statement
22 to keep the product out of reach of children.

23 SEC. 3. Section 4119 of the Business and Professions
24 Code is amended to read:

25 4119. Notwithstanding any other provision of law, a
26 pharmacy may furnish a dangerous drug or dangerous
27 device to a licensed health care facility for storage in a
28 secured emergency pharmaceutical supplies container
29 maintained within the facility in accordance with facility
30 regulations of the State Department of Health Services
31 set forth in Title 22 of the California Code of Regulations
32 and the requirements set forth in Section 1261.5 of the
33 Health and Safety Code. These emergency supplies shall
34 be approved by the facility’s patient care policy
35 committee or pharmaceutical service committee and
36 shall be readily available to each nursing station. Section
37 1261.5 of the Health and Safety Code limits the number
38 of oral dosage form or suppository form drugs in these
39 emergency supplies to 24. This limitation in terms of drug
40 quantities and dosage forms as set forth in Section 1261.5

1 ~~shall not apply to an automated drug delivery system if~~
2 ~~that system provides for security and accountability of~~
3 ~~drug products and there is a function which provides for~~
4 ~~a review of those medications for potential adverse drug~~
5 ~~reactions prior to their withdrawal from the system.~~

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